



Atty. Docket No. A34614 (070050.1690)  
COL IR # 992

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Fisher *et al.*  
Serial No. : 09/515,363 Examiner : Qian, C.  
Filed : February 29, 2000 Group Art Unit: 1636  
For : MELANOMA DIFFERENTIATION ASSOCIATED GENE-  
5 AND PROMOTER AND USES THEREOF

**SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

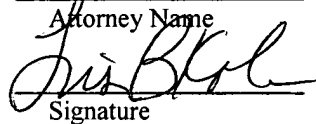
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January 31, 2006

Date of Deposit

Lisa B. Kole

Attorney Name

  
Signature

35,225

PTO Registration No.

January 31, 2006

Date of Signature

Assistant Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In supplement to the Information Disclosure Statements filed on November 14, 2000 and September 22, 2003, and pursuant to the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants respectfully request that the publications relating to the above-mentioned application listed herein and on the accompanying PTO Form 1449 be considered by the Examiner and made of record in the U.S. Patent and Trademark Office.

The publications contained herein, listed in reverse chronological order, are identified as numbers 101 through 133, to distinguish them from the 100 publications

previously disclosed in the above-identified application. The citations listed below are also listed in the accompanying PTO Form 1449.

Full text copies of non-patent publications, foreign Patent documents and foreign published Patent Applications listed herein are enclosed in the accompanying volume of references. Applicants have not enclosed copies of issued U.S. Patents or published U.S. Patent Applications as their submission is not required under 37 C.F.R. § 1.98(a)(2)(ii). Applicants will provide copies of any issued U.S. Patent or published U.S. Patent Application disclosed in this Information Disclosure Statement should the Examiner so require. Reference No. 107 is a copy of a non-US Patent Application published in the French language. An English language translation is not presently available. Applicants will provide an English translation of reference no. 107 should the Examiner so require.

101. Kawai T, et al. (2005) IPS-1, an adaptor triggering RIG-I- and Mda5-mediated type I interferon induction. *Nat Immunol.* 6(10):981-8. Epub Aug 28, 2005.
102. Meylan E, et al. (2005) Cardif is an adaptor protein in the RIG-I antiviral pathway and is targeted by hepatitis C virus. *Nature.* 437(7062):1167-72. Epub Sep 21, 2005.
103. Kang et al., (2004) Expression analysis and genomic characterization of human melanoma differentiation associated gene-5, mda-5: a novel type I interferon-responsive apoptosis-inducing gene. *Oncogene* 23(9):1789-800.
104. Cocude et al. (2003) A novel cellular RNA helicase, RH116, differentially regulates cell growth, programmed cell death and human immunodeficiency virus type 1 replication. *J Gen Virol.* 84(Pt 12):3215-25.

105. Kovacsovics M, et al. (2002) Overexpression of Helicard, a CARD-containing helicase cleaved during apoptosis, accelerates DNA degradation. *Curr Biol.* 2002 May 14;12(10):838-43.
106. Penn et al. (2002) United States Patent Publication No. US-2002/0048763 published April 25, 2002, application serial number 09/864,761 entitled "Human genome-derived single exon nucleic acid probes useful for gene expression analysis."
107. Bahr et al. (2001) International Patent Publication No. WO 01/85955 entitled "RH116 polypeptides and its fragments and polynucleotides encoding said polypeptides and therapeutic uses" published November 15, 2001.
108. Nagano M, et al. (2001) Point mutation (-69 G-->A) in the promoter region of cholesteryl ester transfer protein gene in Japanese hyperalphalipoproteinemic subjects. *Arterioscler Thromb Vasc Biol.* Jun;21(6):985-90.
109. Fisher et al., (2000) United States Patent No. 6,051,376, issued April 18, 2000, entitled "Uses of mda-6."
110. Brenner SE (1999) Errors in genome annotation. *TIG* 15(4):132-133.
111. Huang et al., (1999) Identification and temporal expression pattern of genes modulated during irreversible growth arrest and terminal differentiation in human melanoma cells. *Oncogene* 18:3546-3552.
112. Huang et al., (1999) Differentiation induction subtraction hybridization (DISH): a strategy for cloning genes displaying differential expression during growth arrest and terminal differentiation. *Gene* 236:125-131.
113. Scott et al., (1999) The Pendred syndrome gene encodes a chloride-iodide transport protein. *Nat. Genet.* 21:440-443.
114. Sibson et al., (1999) Genbank Sequence Accession no. A74554, 377 bp linear DNA from International Patent Application No. WO 9401548, sequence release date October 15, 1999.

115. Sibson et al., (1999) Genbank Accession No. A77533, 377 bp linear DNA from European Patent Application No. EP 0587279, sequence released October 19, 1999.
116. Adams MD (1998). Accession Number AQ284992, and corresponding Homology Comparison RESULT #1.
117. Doerks T, Bairoch A, Bork P (1998) Protein annotation: detective work for function prediction. TIG 14(6):248-250.
118. Lin JJ, Jiang H, Fisher PB (1998) Melanoma differentiation associated gene-9, mda-9, is a human gamma interferon responsive gene. Gene 207(2):105-110.
119. Lüking A, Stahl U, Schmidt U (1998) The protein family of RNA helicases. Crit. Rev. Biochem. Mol. Biol. 33(4):259-296.
120. Hofmann K, Bucher P, Tschopp J (1997) The CARD domain: a new apoptotic signalling motif. Trends Biochem. Sci. 22(5):155-156.
121. Su ZZ, Shi Y, Fisher PB (1997) Subtraction hybridization identifies a progression elevated gene PEG-3 with sequence homology to a growth arrest and DNA damage inducible gene. Proc. Natl. Acad. Sci. USA 94:9125-9130.
122. Jiang H, Lin J, Su ZZ, Fisher PB (1996) The melanoma differentiation associated gene-6 (mda-6), which encodes the cyclin-dependent kinase inhibitor p21, may function as a negative regulator of human melanoma growth and progression. Mol. Cell. Different. 4:67-89.
123. Jiang H, Su ZZ, Lin JJ, Goldstein NI, Young CSH, Fisher PB (1996) The melanoma differentiation associated gene mda-7 suppresses cancer cell growth. Proc. Natl. Acad. Sci. USA 93:9160-9165.
124. Rani MR, Foster GR, Leung S, Leaman D, Stark GR, Ransohoff RM (1996) Characterization of beta-R1, a gene that is selectively induced by interferon beta (IFN-beta) compared with IFN-alpha. J. Biol. Chem. 271(37):22878-22884.
125. Jiang H, Lin J, Su ZZ, Herlyn M, Kerbel RS, Weissman BE, Welch DR, Fisher PB (1995) The melanoma differentiation-associated gene mda-6, which encodes the

- cyclin-dependent kinase inhibitor p21, is differentially expressed during growth, differentiation, and progression in human melanoma cells. *Oncogene* 10:1855-1864.
126. Jiang H, Lin JJ, Su ZZ, Goldstein NI, Fisher PB (1995) Subtraction hybridization identifies a novel melanoma differentiation associated gene, mda-7, modulated during human melanoma differentiation, growth, and progression. *Oncogene* 11: 2477-2486.
  127. Anderson et al., (1995) United States Patent No. 5,399,346, issued March 21, 1995, entitled "Gene Therapy."
  128. Waxman, S., ed. (1995) *Differentiation Therapy* (Ares Serono Symposia Publications, Rome). Vol. 10. pp. 1-531. (Table of Contents Only)
  129. Ikeda RA, Ligman CM, Warshamana S. (1992). T7 promoter contacts essential for promoter activity in vivo. *Nucleic Acids Res.* 1992 May 25;20(10):2517-24.
  130. Dreano et al., (1989) European Patent Publication No. 336,523, published Oct. 11, 1989. Method for the in-vivo production and testing of proteins by recombinant gene expression in selected host-cells.
  131. Felgner PL, Gadek TR, Holm M, Roman R, Chan HW, Wenz M, Northrop JP, Ringold GM, Danielsen M (1987). Lipofection: a highly efficient, lipid-mediated DNA-transfection procedure. *Proc. Natl. Acad. Sci. USA* 84:7413-7417.
  132. Rossi P, de Crombrughe B (1987). Identification of a cell-specific transcriptional enhancer in the first intron of the mouse alpha 2 (type I) collagen gene. *Proc. Natl. Acad. Sci. USA* 84:5590-5594.
  133. Ghosh-Choudhury G, Haj-Ahmad Y, Brinkley P, Rudy J, Graham FL (1986). Human adenovirus cloning vectors based on infectious bacterial plasmids. *Gene* 50:161-171.

The submission of this Supplemental Information Disclosure Statement does not represent that a search has been made or that no better art exists, and does not constitute an admission that any of the listed documents are material or constitute "prior art." If the

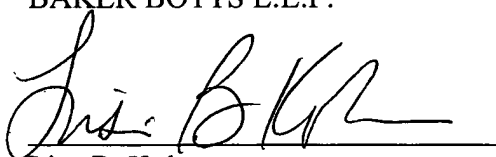
Examiner applies any of the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

Applicants believe no fee is required for submission of this Supplemental Information Disclosure Statement because it is filed before mailing of the first Office Action following a Request for Continued Examination of the present Application. If any other fee is required in connection with this communication or any overpayment has been made, please charge any deficiency or credit any overpayment to Deposit Account No. 02-4377. Two copies of this communication are enclosed.

Respectfully submitted,

BAKER BOTTS L.L.P.

A handwritten signature in black ink, appearing to read "Lisa B. Kole", written over a horizontal line.

Lisa B. Kole

Patent Office Reg. No. 35,225

Attorneys for Applicants  
(212) 408-2500

Enclosures

<b>Form PTO-1449 U.S. Department of Commerce</b> <b>(REV. 2-82) Patent and Trademark Office</b>  <b>INFORMATION DISCLOSURE STATEMENT</b> <b>BY APPLICANT</b> (Use several sheets if necessary)	Atty. Docket No. A34614 - 070050.1690	Serial No. 09/515,363
	Applicant Fisher et al.	
	Filing Date February 29, 2000	Group 1636
	Examiner C. Qian	

### U.S. PATENT DOCUMENTS

*Exam. Initial.	No.	Document No.	Date	Name	Class	Subclass	Filing Date if Approximate.
	106	2002/0048763	April 25, 2002	Penn et al.			
	109	6,051,376	April 18, 2000	Fisher et al.			
	127	5,399,346	March 21, 1995	Anderson et al.			

### FOREIGN PATENT DOCUMENTS

Exam Initial	No.	Document No.	Date	Country	Class	Subclass	<u>Translation</u> Yes No
	107	WO 01/85955	Nov. 15, 2001	WO			
	130	336,523	Oct. 11, 1989	EPO			

Exam Initial	No.	OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)
	101	Kawai T, et al. (2005) IPS-1, an adaptor triggering RIG-I- and Mda5-mediated type I interferon induction. Nat Immunol. 6(10):981-8. Epub 2005 Aug 28.
	102	Meylan E, et al. (2005) Cardif is an adaptor protein in the RIG-I antiviral pathway and is targeted by hepatitis C virus. Nature. 437(7062):1167-72. Epub 2005 Sep 21.

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\* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	129	Waxman, S., ed. (1995) <i>Differentiation Therapy</i> (Ares Serono Symposia Publications, Rome). Vol. 10. pp. 1-531. (Table of Contents Only)
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